K050546

MAY 2 0 2005

510(k) Summary

Device Names:

ACON +/- Midstream Pregnancy Test

Common Name:

Pregnancy Test Kit, Over-the-Counter

Classification Number:

862.1155

FDA Product Code:

LCX

Medical Specialty:

Clinical Chemistry

Intended Use:

The ACON +/- Midstream Pregnancy Test is for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter use.

Device Description:

ACON +/- Midstream Pregnancy Test is a modified device from the previously FDA-cleared ACON Midstream Pregnancy Test (K983090). The immunochemical formulation, which employs an antibody-antigen-antibody color particle sandwich binding, lateral flow immunoassay for the detection of hCG, remains the same for the modified device. With the incorporation of a proprietary moisture-sensitive dye pad within the test strip, an additional test line perpendicular to the regular test line will develop for the modified test device. The moisture-sensitive dye on the dye pad will change from colorless to pink/red color when wet by urine sample. Regardless of the test result, this perpendicular line will always be visible to the user. While the un-modified device will have a colored test line developed in the result window for positive result and no colored line for negative result, this modified test device will have a colored "+" pattern in the result window for positive result, and a colored "-" pattern for negative result.

Therefore, a colored "+" sign forms in the result window indicates a **positive** result; while the presence of a "-" sign in the result window indicates a **negative** result. To serve as a procedural control, a red line will always appear in the control window, indicating adequate sample volume and proper wicking, regardless of the presence of hCG in the urine sample. The absence of the red control line in the control window indicates that the test result is "**invalid**". For the modified device, the absence of a horizontal line in the result window also constitutes an "**invalid**" test result even there is a red line present in the control window.

The ACON +/- Midstream Pregnancy Test qualitatively detects hCG in urine sample with a designated cutoff hCG concentration of 25 mIU/mL. The cutoff concentration of this test has been standardized to the World Health Organization Fourth International Standard for Chorionic Gonadotropin (NIBSC Code: 75/589). The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), or TSH (1,000 μIU/mL) to either negative (0 mIU/mL hCG) or positive (25 mIU/mL hCG) urine samples did not interfere in correctly reading of the expected test result.

Clinical Study:

A device readability study using the ACON +/- Midstream Pregnancy Test by participants with no laboratory experience demonstrated an accuracy of over 99% (259/260 with 95% confidence interval of 97.9-99.9%), indicating that the vast majority of lay persons are able to correctly read and interpret the test results following the package insert's instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 0 2005

Edward Tung, Ph.D.
Regulatory Affairs
ACON Laboratories Inc.
4108 Sorrento Valley Blvd
San Diego, CA 92121

Re: k050546
Trade/Device Name: ACON +/- Midstream Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: May 2, 2005
Received: May 3, 2005

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K050546

Device Name: ACON +/- Midstream Pregnancy Test

"Indications for Use": The ACON +/- Midstream Pregnancy Test is intended for over-the-counter use for the qualitative identification of the elevated level of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050546